**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicants: S. NAKATA et al.

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For: AUTOMATIC ANALYZING APPARATUS

Art Unit: 1743

Examiner: L. Alexander

June 23, 2008

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

    This Appeal Brief is responsive to the Final Rejection mailed

August 24, 2007. In accordance with 37 CFR §41.37, the Appellants address the

following items.

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Identification Page

I.   **REAL PARTY IN INTEREST**

The real party in interest in this application is the assignee of record,

Hitachi, Ltd.

II.   <u>RELATED APPEALS AND INTERFERENCES</u>

There are no related prior or pending appeals, judicial proceedings or interferences known to the appellant which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III.   <u>STATUS OF CLAIMS</u>

Claims 1-3, 6 and 8-12 are currently pending. Claims 1-3, 6 and 8-12 have been finally rejected and are the subject of this appeal. Claims 4, 5, 7 and 13-15 have been canceled without prejudice or disclaimer.

IV.   **STATUS OF AMENDMENTS**

All previously filed amendments have been entered. No amendments
have been filed subsequent to the final rejection.

V.   <u>**SUMMARY OF CLAIMED SUBJECT MATTER**</u>

The present invention solves a need in the prior art for an analysis information management method using a service center connected through communication lines to a plurality of automatic analyzing apparatuses used in a plurality of facilities, which ensures that correct analysis parameters for testing items to be analyzed are readily set, thereby improving the efficiency and reliability for the testing conducted by the automatic analyzing apparatuses.

The prior art has known automatic analyzing apparatuses that perform chemical reactions between samples and reagents, to quantitatively measure contents of the samples. Analysis parameters must be set to the automatic analyzing apparatuses, by which analysis of the samples take place. "Analysis parameters" refers to parameters for testing items in the automatic analyzing apparatuses, and may include information such as the amount of dispensed sample, reagents used for analysis and amount thereof, wavelength of absorbance under measurement, type of reaction process, method of calculating a concentration, a standard sample and known concentration for use in calibration, and the like. Specification at page 1, line 13 – page 2, line 2.

In particular, information relating to reagents may differ from one reagent to another depending on reagent manufacture, even for reagents used for analyzing the same testing item. In addition, the contents of analysis parameters may result in different information for different manufacturing lots. Thus, analysis parameters set to the automatic analyzing apparatuses must be the latest

analysis parameters for the reagents set in the automatic analyzing apparatuses.
Specification at page 2, lines 2-11.

Prior efforts at setting analysis parameters include manual setting of such
parameters through a keyboard or the like, and providing analysis parameters on
a barcode attached to the reagent containers, for reading by a barcode reader.
Manual setting of analysis parameters requires numerous input steps, and is
subject to error. Further, reagent suppliers must set analysis parameters for all
automatic analyzing apparatuses in all testing facilities to which their reagents
are supplied, correspondingly multiplying the number of steps and the probability
of error. Barcodes attached to reagent containers may alleviate some of these
problems, but the barcodes themselves must be attached to the reagent
containers, and the user operating the automatic analyzing apparatuses in which
the analysis parameters have been set via the barcodes must have technical
knowledge for determining whether the settings have been correctly made.

The present inventors provide an analysis information management
method that reduces or avoids these and other problems, using a service center
connected to a plurality of automatic analyzing apparatuses via communication
lines, including plural facilities each having automatic analyzing apparatuses.
The service center has a database for storing analysis parameters related to a
plurality of reagents for use in the automatic analyzing apparatuses used in the
plurality of facilities.

More particularly, with reference to the present specification and drawing,
Fig. 1 is a block diagram illustrating the configuration of an analysis information

management system which use the analysis information management method according to one embodiment of the present invention. A service center 10 is connected to automatic analyzing apparatuses 100A, 100B . . . , 100Z in testing facilities 1, . . . M, through communication lines L. Each of the testing facilities has one or more automatic analyzing apparatuses 100. The service center 10 is also connected to a plurality of reagent suppliers 20A, 20B, . . . 20N through communication lines L. Specification at page 6, lines 14-25.

The service center 10 disclosed in Fig. 1 comprises a communication unit 12, an analysis information parsing unit 14, a database 16, and a reagent parameter registration unit 18. In this embodiment, the service center 10 manages analysis information, such as analysis parameters related to reagents, and communicates effectively with the reagent suppliers 20 and automatic analyzing apparatuses 100 in the various testing facilities, incorporating the results of analyses by the various apparatuses to insure and improve the accuracy thereof. Specification at page 6, line 26 – page 7, line 5.

The communication unit 12 transmits and receives analysis information to and from the automatic analyzing apparatuses 100 via the communication lines L. The analysis information parsing unit 14 evaluates and parses analysis information such as the results of analyses sent from the automatic analyzing apparatuses 100. The database 16 stores data for managing the reagents available to the automatic analyzing apparatuses 100 and analysis parameters related to the reagents, an analysis information of the associated automatic analyzing apparatuses 100. Such information includes information concerning

the reagents used in analyses and analysis parameters, results of calibrations, results of analyses on accuracy management (control) samples. The reagent parameter registration unit 18 stores information related to reagents, such as names of testing items under analysis, analysis parameters related to the reagents, and automatic analyzing apparatuses available with the reagents. Specification at page 7, lines 6-28.

The reagent suppliers 20 supply reagents to the respective testing facilities. The reagent suppliers 20 register reagent and analysis parameter information with the database 16 of the service center 10 via communication lines L and the reagent parameter registration unit 18, including any newly added, updated, or changed reagents, so that the service center 10 has the most recent information related to the reagents. Specification at page 8, lines 1-14.

In each automatic analyzing apparatus 100, analysis parameters must be set for the testing items which are to be analyzed using reagents set in the automatic analyzing apparatus 100 before starting the analysis. When a reagent is newly supplied from a reagent supplier 20 into the automatic analyzing apparatus 100, in particular, analysis parameters associated with the reagent may not have been set previously in the automatic analyzing apparatus 100. In this event, it is necessary to obtain the analysis parameters and to set the obtained analysis parameters into the automatic analyzing apparatus 100 for the new reagent. To this end, the automatic analyzing apparatus 100 requests the service center 10 to send a list on which available reagents can be viewed by the user of the automatic analyzing apparatus. In response to the request, the

service center 10 searches its database 16 to create a list of reagents available in the automatic analyzing apparatus 100, which has made the request, and transmits the list to the requesting automatic analyzing apparatus 100 through the communication lines L. The received reagent list can be displayed at the automatic analyzing apparatus 100 for the user to select a reagent therefrom, upon which the automatic analyzing apparatus 100 transmits the selection to the service center 10 which retrieves associated analysis parameters from its database 16, if possible. The retrieved analysis parameters are then sent to the automatic analyzing apparatus 100 to be set therein. Specification at page 8, line 15 – page 9, line 14.

In the automatic analyzing apparatus, reagents are typically provided in reagent bottles that may or may not have a barcode attached to the side surface thereof. A reagent barcode often includes reagent bottle identification information, reagent lot number, expiration date and the like. Specification at page 12, line 26- page 13, line 1. As illustrated in Fig. 2, when reagent barcode readers 132A, 132B are provided, barcodes are read from reagent bottles at all positions on the reagent disks 130A, 130B, thereby registering reagent bottle information corresponding to the reagent bottle at each position. On the other hand, when barcodes are not provided to the bottles, the reagent bottle information must be registered by the user, who manually enters the information using a manipulation panel 176. The reagent bottle information includes, for example, type of reagent, lot number, expiration date, remaining amount of reagent and the like. Specification at page 12, lines 1-13.

Testing items that can be analyzed are determined in accordance with the reagents set in the reagent disks 130A, 130B, and analysis parameters are required for defining the analysis conditions for the testing items and reagents therefor.

Referring now to Fig. 3, at step S200, the user sets reagent bottles on the reagent disks 130A, 130B of an automatic analyzing apparatus 100, whereupon microcomputer 160 of the automatic analyzing apparatus 100 causes barcodes on the reagent bottles to be read at all positions on the reagent disks 130A, 130B by the barcode readers 132A, 132B.

Then, at step S205, the microcomputer 160 searches stored reagent bottle information and analysis parameter information from the read barcode information. Specification at page 14, lines 7-16.

Fig. 4 shows an example of a display screen showing reagent information related to the regent set at each position on the reagent disks. The reagent information screen 172A shown in Fig. 4 provides the position, testing item, reagent type, reagent lot number , reagent bottle number, presence/absence of analysis parameters, and reagent information serial number for each position. The example shown in Fig. 4 indicates reagent sat at Position 1 has a testing item name "AP", reagent type R1, reagent lot number "10001" and analysis parameters "present". Reagent information screen 172A indicates that the reagent at position 3 does not have corresponding analysis parameters entered in the automatic analyzing apparatus 100. The reagent information screen 172A further indicates no information regarding the reagent at position 4. In particular,

this suggests that the reagent bottle at position 4 has no barcode. Specification at page 14, line 27 – page 15, line 18.

At Step S210, in the absence of a barcode on the reagent bottle, the operator enters information which allows identification of the reagent. For example, the operator may enter the reagent lot number or the like in the appropriate blank field on the reagent information screen 172A. The microcomputer 160, determining that reagent barcode information has been manually entered, searches stored reagent bottle information for information on the entered reagent, and displays the retrieved information, if found, on the reagent information screen 172A (step S215). If analysis parameters also have been stored for a testing item which is analyzed with the searched reagent, "presence" is displayed in the appropriate presence/absence field on the reagent information screen 172A. When no associated analysis parameters have been stored, however, such as when a novel reagent is set, the reagent information screen 172A indicates the absence of the analysis parameters, in which case the analysis parameters must be set before analysis is started. In this event, the operator depresses a "reagent list download button" positioned in the lower right region in the reagent information screen 172A illustrated in Fig. 4. Specification at page 16, lines 1-16.

At Step S220, the microcomputer 160 determines whether the operator has instructed to download the reagent list. At Step S225, because the reagent list download button has been depressed, the microcomputer 160 transmits a reagent list download request to the service center 10 through the

communication line L. In this event, the microcomputer 160 also transmits

identification information of the automatic analyzing apparatus 100, such as its

model number, to the service center 10. The service center 10 searches for all

reagents available in the automatic analyzing apparatus 100 that made the

reagent list download request, collects the reagents in the form of a list, and

transmits the list to the automatic analyzing apparatus 100 through the

communication line L. Specification at page 16, line 17 – page 17, line 7.

　　　Upon completion of the downloading, the microcomputer 160 displays the

reagent list, such as that shown in Fig. 5, as a reagent list screen 172B, at Step

S235. Specification at page 17, lines 8-13.

　　　The reagent list screen 172B may show the reagent information serial

number, reagent maker name, testing item, reagent lot number, and the like.

Specification at page 17, lines 19-21. The operator views this reagent list to

search for a reagent for which analysis parameters must be newly set, and

enters the testing item name and reagent information serial number in the

corresponding fields at the corresponding positions on the reagent screen. For

example, for the reagent at position 4 in Fig. 4, testing item name "AST", reagent

lot number "00001", and reagent information serial No. "2001" in the appropriate

fields in registration screen information 172A in Fig. 4. This causes information

such as reagent type, reagent lot number, and the like to be entered

automatically. This processing is performed for all reagents for which analysis

parameters have not been stored and therefore must be newly set. Upon

completion of this processing, the operator depresses a "parameter download

button" in a lower right region on the reagent information screen 172A in Fig. 4.

Specification at page 17, line 21 – page 18, line 14. At Step S240, the

microcomputer 160 determines whether the operator has selected reagent

information, or instructed to download analysis parameters. When the operator

has selected reagent information or instructed to download analysis parameters,

the microcomputer 160 creates an analysis parameter download request which is

transmitted to the service center 10 through the communication line L at Step

S245. The service center 10 searches for all analysis parameters requested for

downloading and transmits the analysis parameters to the automatic analyzing

apparatus 100. Specification at page 18, line 15 – page 19, line 1.

Upon completion of the downloading, the microcomputer 160 stores the

received analysis parameters at Step S255, and indicates the "presence" of the

analysis parameters at the associated position for the corresponding reagent in

the reagent information screen 172A shown in Fig. 4. Specification page 19,

lines 2-10. Upon the microcomputer 160 determining whether an analysis start

key has been depressed (Step S260), analysis parameters are stored in the

memory of the microcomputer 160 for conducting the analysis based thereon, at

Step S265. Specification at page 19, lines 11-16.

The automatic analyzing apparatus 100 conducts the analysis based on

the analysis parameters set at Step S265. In particular, when a new reagent has

been introduced and analysis parameters associated therewith have been newly

set, the operator performs a calibration to create a calibration curve before an

accuracy management (control) sample is analyzed. The microcomputer 160

transmits the result of calibration and the result of analysis of the control sample as well as analysis information such as reagents used therein and analysis parameters to the service center 10 through the communication line L. Specification at page 20, lines 15-26.

Upon receipt of the analysis information from each automatic analyzing apparatus 100 through the communication unit 12, the service center 10 classifies the received analysis information by testing facility or automatically analyzing apparatus, and saves the classified analysis information in the database 16 for management. The analysis information parsing unit 14 of the service center 10 retrieves the results of the analyses on the control samples measured using the same reagent, managed in the database 16, and calculates an average value which is defined as a standard value. Then, upon determination that the currently received result of analysis on the control sample has been acquired using newly set analysis parameters, the analysis information parsing unit 14 calculates a deviation between the previously found standard value and the currently received analysis result, and determines whether the deviation is within an allowable range. If the deviation is outside the allowable range, the analysis information parsing unit 14 confirms, for example, whether correct analysis parameters were used for reagents used in the analysis, whether the set analysis parameters are inconsistent with the contents, and the like. Then, the analysis information parsing unit 14 creates a report which summarizes the result of verification, countermeasures to be taken by the operator, and the

like, and transmits the report to the automatic analyzing apparatus 100.
Specification at page 20, line 28 – page 21, line 26.

The operator receiving the report relies on the contents to start testing, or to take appropriate action in the indication of a defect, for example.

According to the present invention, therefore, analysis information, such as the information on the results of measurements made by the automatic analyzing apparatus, is transmitted to the service center, where results are parsed and evaluated. The service center, receiving and evaluating such analysis information from plural automatic analyzing apparatuses in plural testing facilities, can therefore verify the operation of an individual automatic analyzing apparatus from a global viewpoint and thereby support the user of the automatic analyzing apparatus who does not have a high level of technical knowledge, so that the user can readily verify that analysis parameters have been correctly set. Specification at page 22, lines 5-13. Accordingly, even when there are a plurality of facilities having a plurality of automatic analyzing apparatuses using reagents from a plurality of reagent suppliers, and even if the reagent containers do not have barcodes attached thereto for allowing identification of the reagents therein, it is possible to readily set analysis parameters for testing items to be analyzed using the reagents, and to readily verify that the analysis parameters have been correctly set, thereby improving the efficiency and reliability for the testing work conducted by the automatic analyzing apparatus. Further, when viewed from the reagent suppliers, there is an improvement in the efficiency in the distribution of analysis parameters to testing facilities and the like.

Claim 1 is the only independent claim.

A.   Summary of the Subject Matter of Independent Claim 1

Claim 1 recites an analysis information management method using a service center connected through communication lines to a plurality of automatic analyzing apparatuses used in a plurality of facilities, the service center having a database for storing analysis parameters related to a plurality of reagents for use in the plurality of automatic analyzing apparatuses used in the plurality of facilities. According to the method, responsive to a request from one of the automatic analyzing apparatuses, the service center creates a list of reagents available in the requesting automatic analyzing apparatus from information on reagents stored in the database, and supplies the automatic analyzing apparatus with the list through a communication line. The Appellants refer to Fig. 1 (service center 10, automatic analyzing apparatus 100, communication line L, database 16); Fig. 3 (Steps S220 and S225); and the specification from page 16, line 17 – page 17, line 7. The service center transfers analysis parameters, according to which a test is to be carried out on a testing item to be analyzed using a reagent selected from the list, to the automatic analyzing apparatus through the communication line, responsive to the selection of the associated reagent from the list. The Appellants refer to Fig. 3 at Steps S240 and S245, and the specification at page 18, lines 15-21.

Further, according to claim 1, the service center classifies and stores information, including results of calibrations measured by the automatic analyzing

apparatuses, results of analyses on control samples, reagents used in analyses, and analysis parameters, for tests carried out in each facility or for each automatic analyzing apparatus, wherein the results of analyses on the control samples are derived from analyses of the control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center. The Appellants refer to the present specification from page 20, line 28 – page 21, line 5. Further, the service center calculates a statistical standard value defined for the results of analyses on the control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center, based on the stored information on the results of analyses for each facility or for each automatic analyzing apparatus. A description supporting this feature is found on page 21, lines 5-10.

The selected reagent is added to a control sample in the automatic analyzing apparatus, the control sample is analyzed by the automatic analyzing apparatus, the service center calculates the statistical deviation for the result of analysis for the standard value for evaluation, and it is determined whether the analysis parameters used in the analysis are correct, based on the calculated statistical deviation. A supporting description is found in the specification on page 21, lines 11-18.

The references to the specification are to show support for the claimed subject matter, as required by 37 CFR §41.37, and are not to be considered unduly limiting of the scope of any claim, including claim 1.

VI. **GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

A. Claims 1-3, 6, and 8-12 are rejected under 35 U.S.C. §102(b) as being anticipated by JP 5-288756 (JP '756).

B. Claims 1-3, 6, and 8-12 are rejected under 35 U.S.C. §102(b) as being anticipated by JP 4-128657 (JP '657).

C. Claims 1-3, 6, and 8-12 stand rejected under 35 U.S.C. §102(e) as being anticipated by Fritchie, U.S. Patent No. 6,022,746 (Fritchie).

VII.   ARGUMENT

References Relied Upon by the Examiner

Japanese Patent Application Publication No. 5-288756 (JP '756)

Japanese Patent Application Publication No. 4-128657 (JP '657)

Fritchie, U.S. Patent No. 6,022,746 (Fritchie)

A. Claims 1-3, 6, and 8-12 are rejected under 35 U.S.C. §102(b) as being anticipated by JP 5-288756 (JP '756).

Claim 1

Claim 1 recites an analysis information management method using a service center connected through communication lines to a plurality of automatic analyzing apparatuses used in a plurality of facilities. The service center has a database for storing analysis parameters related to a plurality of reagents for use in the plurality of automatic analyzing apparatuses used in the facilities.

According to the method, the service center responds to a request from one of the automatic analyzing apparatuses ("the requesting automatic analyzing apparatus"), to create a list of reagents available in the requesting automatic analyzing apparatus. The list of reagents is created from information on reagents stored in the database, and the service center supplies the list to the requesting automatic analyzing apparatus through a communication line.

Responsive to a selection of an associated reagent from the list, made by a user of the automatic analyzing apparatus, the service center transfers analysis

parameters, according to which a test is to be carried out on a testing item to be analyzed using the selected reagent. The service center transfers the analysis parameters to the requesting automatic analyzing apparatus from which the reagent was selected.

Additionally, the service center classifies and stores information including results of calibrations measured by the plurality of automatic analyzing apparatuses, results of analyses on control samples, reagents used in analyses, and analysis parameters, for tests carried out in each facility or for each automatic analyzing apparatus. The Appellants note that the results of analyses on the control samples are derived from analyses of the control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center, as claimed in claim 1.

Based on the stored information on the results of analyses for each facility or for each automatic analyzing apparatus, the service center calculates a statistical standard value defined for the results of analyses on the control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center.

Continuing, the method adds the selected reagent to a control sample in the automatic analyzing apparatus that initially requested creation of the list of reagents. The control sample is analyzed by the automatic analyzing apparatus, a statistical deviation for the result of analysis is calculated by the service center from the standard value, and based on the calculated statistical deviation, it is determined whether the analysis parameters used in the analysis are correct.

In accordance with these method steps, because a standard value for results of analyses on control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center is calculated, and a statistical deviation therefrom is calculated, the results can be used to verify that the analysis parameters used in the analysis are correct. This also helps determine whether there is some defect in the automatic analyzing apparatus.

Japanese Patent Application Publication No. 5-288756 discloses an automatic analyzer and system which can input a parameter related to analysis into the automatic analyzer from an external computer. Respectfully, however, such is the extent to which JP '756 is particularly pertinent to the previously-advanced arguments for patentability of claim 1.

Indeed, perhaps due to the deficiency, the final rejection does not seem to address all limitations of claim 1 in the application of JP '756. In this regard, the Appellants have noted that page 2 of the Office Action indicates that the Examiner may not fully understand the claimed invention (the Examiner also cites alleged 35 U.S.C. §112, second paragraph issues, but it is believed that all such issues have been resolved at this stage of the prosecution). Thus, in rejecting claim 1, "the Examiner best understands the invention as a network of automatic analyzer devices connected to a central server. When a specific analysis is selected for the specific device, this information is sent to the server. In return, the server supplied calibration information/data to properly set the parameters in the device."

With this somewhat rudimentary assessment of the claimed invention, JP '756 is cited as teaching a system to automatically transfer various kinds of parameters from an automatic analyzer, the Examiner referring to sample identifying means 3, reagent identifying means 10, and communication means 30, 31, 32 from the English translation of the abstract. However, these features alleged in JP '756 are not applied to the limitations of claim 1. Indeed, the paragraph bridging pages 2 and 3 of the final rejection is a substantial copy of the English-translated "CONSTITUTION" on the Patent Abstract supplied by the Japan Patent Office, without an attempt to read the claim limitations on the abstract.

The Appellants thus assert that the rejection is based upon an insufficient interpretation of the claims that does not include all of the claim limitations. In particular, the rejection does not show how or where the creating step of claim 1 is read on the JP '756 disclosure. There is no disclosure in JP '756 that the external computer 29 (or any structure corresponding to the claimed service center) creates a list of reagents available in a requesting automatic analyzing apparatus, from information stored in a database in the service center, responsive to a request from the automatic analyzing apparatus. The final rejection also does not show where JP '756 discloses that the list of reagents is supplied to the requesting automatic analyzing apparatus through a communication line.

In addition, JP '756 does not show that the external computer 29 or any other service center transfers analysis parameters to the automatic analyzing

apparatus through the communication line, responsive to selection of an associated reagent from the list, made by a user of the automatic analyzing apparatus. The final rejection asserts that the abstract of JP '756 "teach[es] an external computer (29) that controls all of the data handling, transfer and analysis" (Final Rejection at page 4), although the abstract in fact only mentions that a parameter related to the analysis determined by the reagent and such parameters as the concentration, calibration curve, etc. of a standard sample to be used for calibration or the like are taken into the automatic analyzer from the external computer 29. There is no mention of the creating or transferring steps set forth in claim 1.

Further, claim 1 requires that the service center classify and store information, including results of calibrations measured by the automatic analyzing apparatuses, results of analyses on control samples, reagents used in analyses, and analysis parameters, for tests carried out in each facility or for each automatic analyzing apparatus, wherein the results of analyses on the control samples are derived from analyses of the control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center. JP '756 does not disclose that external computer 29 classifies and stores such results and analysis parameters.

In addition, to the extent that external computer 29 may appear to store results or analysis parameters corresponding to those claimed, the final rejection does not show that JP '756 classifies and stores results and analysis parameters corresponding to those claimed, for tests carried out <u>in each facility or for each</u>

automatic analyzing apparatus, wherein the results of analyses on the control samples are derived from analyses of the control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center. The Appellants note that the claimed method is performed using a service center connected through communication lines to a plurality of automatic analyzing apparatuses used in a plurality of facilities.

Claim 1 further recites that the service center calculates a statistical standard value defined for the results of analyses on the control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center, based on the stored information on the results of analyses for each facility or for each automatic analyzing apparatus. Necessarily, because JP '756 does not disclose the stored information on the results of analyses for plural facilities or for plural automatic analyzing apparatuses, it follows that the claimed calculating step is not performed by external computer 29 or any other alleged service center in JP '756. Moreover, the final rejection asserts simply that JP '756 teaches that external computer 29 "calculates all the parameters of sample standard that is used for calibration," without citing any passage that supports this statement, or that calculates a statistical standard value at all.

Furthermore, claim 1 recites that the selected reagent is added to a control sample in the requesting automatic analyzing apparatus, and analyzes the control sample by the requesting automatic analyzing apparatus, wherein the service center calculates a statistical deviation for the result of analysis from the

standard value, and determines, based on the calculated statistical deviation, whether the analysis parameters used in the analysis are correct. These limitations are ignored in the final rejection, and indeed, JP '756 does not disclose them.

For each of the foregoing reasons, the Appellants respectfully submit that claim 1 is not anticipated by JP '756, and request reversal of the final rejection.

Claim 2

Dependent claim 2 further limits the analysis information management method of claim 1 by requiring the automatic analyzing apparatus to automatically set the transferred analysis parameters. The final rejection does not address this feature of the invention, and thus no *prima facie* case has been established for the rejection of claim 2. Accordingly, the Appellants request reversal of the rejection of the dependent claim 2.

Claim 3

Dependent claim 3 further limits the analysis information management method of claim 1 by requiring the database stored in the service center to store analysis parameters related to reagents from a plurality of reagent suppliers. The final rejection does not address this claim with specificity, and thus no *prima facie* case of unpatentability has been made out. Accordingly, the Appellants respectfully request reversal of the rejection of claim 3.

Claim 6

Dependent claim 6 further limits the analysis information management method of claim 1 by requiring that, when a reagent supplier supplies a novel reagent or a reagent in a new lot to a user of the requesting automatic analyzing apparatus, the reagent supplier registers the database stored in the service center with information related to the reagent, such as the reagent, automatic analyzing apparatuses capable of using the reagent, and analysis parameters for the reagent prior to supply. The final rejection does not address the limitations of claim 6 with any specificity, and thus no *prima facie* case of anticipation is made out. Accordingly, the Appellants respectfully request reversal of the rejection of claim 6.

Claim 8

Dependent claim 8 further limits the analysis information management method of claim 1 by requiring the service center, upon determination that the result of analysis on an accuracy management sample transferred thereto from the automatic analyzing apparatus was derived using newly set analysis parameters, to summarize the result of determination in a report, and to transmit the report to the automatic analyzing apparatus through the communication line. The final rejection does not address the limitations of claim 8, and thus no *prima facie* case of anticipation is made out. Accordingly, the Appellants respectfully request reversal of the rejection of claim 8.

Claim 9

Dependent claim 9 further limits the analysis information management method defined in claim 1, by requiring that each time the service center receives the result of analysis on a control sample from the requesting automatic analyzing apparatus, the service center calculates the statistical deviation from the standard value, and transmits the results of analysis to the requesting automatic analyzing apparatus through the communication line if any defect is recognized based on the determination. The final rejection does not address the limitations of claim 9, and thus no *prima facie* case of anticipation is made. Accordingly, the Appellants respectfully request reversal of the rejection of claim 9.

Claim 10

Dependent claim 10 further limits the analysis information management method of claim 9 by requiring that, when no defect is recognized in the result of analysis, the service center stores the result of analysis, periodically creates a report, and transmits the report to the automatic analyzing apparatuses through the communication lines. The limitations of claim 9, however, are not addressed in the final rejection, and thus no *prima facie* case of anticipation is made. Accordingly, the Appellants respectfully request reversal of the rejection of claim 10.

Claim 11

Dependent claim 11 further limits the analysis information management method of claim 1, by requiring the service center to periodically calculate the standard value, and to transmit the standard value to the automatic analyzing apparatuses through the communication lines as technical information. The limitations of claim 11 are not addressed in the final rejection, however, and thus no *prima facie* case of anticipation is established. Accordingly, the Appellants respectfully request reversal of the rejection of claim 11.

Claim 12

Dependent claim 12 further limits the analysis information management method of claim 1 by requiring the service center to store and manage, by version, programs for controlling the automatic analyzing apparatuses administered thereby, and to automatically install a program of a requested version in response to a request from an automatic analyzing apparatus administered thereby. The final rejection, however, does not address the limitations of claim 12, and particularly does not assert any passage in JP '756 relating to the storing, managing by version, or installation of any program for controlling the automatic analyzing apparatuses administered by the service center. Accordingly, the Appellants respectfully request reversal of the rejection of claim 12.

B. Claims 1-3, 6 and 8-12 stand rejected under 35 U.S.C. §102(b) as being

anticipated by Japanese Patent Application Publication No. 4-128657 (JP '657).

Claim 1

The Appellants refer to the summary of claim 1 set forth above. The final

rejection also fails to show that JP '657 anticipates the invention claimed in

claim 1.

In particular, the step of creating a list of reagents available in the

requesting automatic analyzing apparatus, from information on reagents stored in

the service center database, in response to the request from the automatic

analyzing apparatus, is not shown by JP '657. JP '657 discloses an analytical

system whose stated purpose is to enable the same condition as that at the time

of analysis, by treating parameters for determining analytical conditions and the

results of analysis as a set, wherein the conditions for operating respective

analytical devices on a network are stored in a transmission parameter table 4 of

a computer 1 connected to the plurality of analytical devices, and wherein the

conditions are sent to the respective analytical devices at the start of analysis.

After completion of analysis, the results of analysis and the contents of the

parameter tables stored in the analytical devices are sent to the computer 1

automatically or by instruction of the analyzer. JP '657 does not disclose

creation of a reagent list responsive to a request from any of the analytical

devices, or supplying the requesting automatic analyzing apparatus with the list.

The final rejection asserts that JP '657 discloses that an unspecified "output" is returned to any of the devices on the network "after treating the parameters" to determine if the analytical conditions and the results of analysis are valid. Based on the "PURPOSE" of the Japan Patent Office abstract, it appears that the "output" referenced in the final rejection is an output of the computer 1, but neither the abstract nor the final rejection supports the statement that "parameters" are "treated" to determine whether analytical conditions and results of analysis are valid. Further, the "output" does not appear to be a reagent list created in accordance with claim 1.

Furthermore, claim 1 requires the service center to transfer analysis parameters, according to which a test is to be carried out on a testing item to be analyzed using a selected reagent, to the requesting automatic analyzing apparatus, wherein the selection of an associated reagent is made from the reagent list by a user of the automatic analyzing apparatus. JP '657 neither discloses nor suggests the selection of a reagent from a list by the analyzer user, or that analysis parameters are transferred in response to such a selection. Rather, the final rejection simply repeats verbatim the "CONSTITUTION" of the Japan Patent Office abstract, and asserts on page 4 of the final rejection that the computer 1 maintains operating conditions and parameter tables, and stores "subsequent results" from analytical devices 6 and 10 to prevent errors.

Additionally, as noted above, claim 1 requires the service center to classify and store information, including results of calibrations measured by the automatic analyzing apparatuses, results of analyses on control samples, reagents used in

analyses and analysis parameters, for tests carried out <u>in each facility or for each automatic analyzing apparatus</u>, wherein the results of analyses on the control samples are derived from analyses of the control samples using the same reagents <u>in all automatic analyzing apparatuses in all facilities administered by the service center</u>. JP '657, however, does not disclose the classification or the storing of all the information as claimed, and does not disclose that such information is stored for tests carried out in each facility or for each automatic analyzing apparatus, wherein the results of analyses on the control samples are derived from analyses of the control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center.

In addition, while claim 1 requires the service center to calculate a statistical standard value defined for the results of analyses on the control samples using the same reagents <u>in all automatic analyzing apparatuses in all facilities administered by the service center</u>, based on the stored information on the results of analyses <u>for each facility or for each automatic analyzing apparatus</u>, JP '657 has no such teaching. Furthermore, the final rejection does not allege a disclosure in JP '657 corresponding to the claimed calculating step.

Further, claim 1 requires the selected reagent to be added to the control sample in the requesting automatic analyzing apparatus, and a step of analyzing the control sample by the requesting automatic analyzing apparatus. Claim 1 also requires the service center to calculate a statistical deviation for the result of analysis from the standard value, and a step of determining, based on the

calculated statistical deviation, whether the analysis parameters used in the analysis are correct. Although the final rejection alleges that the unspecified "output" is returned to any of the analytical devices on the network after treating the parameters to determine if the analytical conditions and the results of analysis are valid, as noted above, JP '657 does not seem to support the allegation. Indeed, these steps are not disclosed or fairly suggested by JP '657, and in particular, JP '657 does not seem to perform these steps with respect to control samples so as to assure that analysis parameters used in the analysis are correct.

For each of the foregoing reasons, the Appellants respectfully submit that JP '657 does not anticipate the invention claimed in claim 1.

Claim 2

Dependent claim 2 further limits the analysis information management method of claim 1 by requiring the automatic analyzing apparatus to automatically set the transferred analysis parameters. The final rejection does not address this feature of the invention, and thus no *prima facie* case has been established for the rejection of claim 2. Accordingly, the Appellants request reversal of the rejection of the dependent claim 2.

Claim 3

Dependent claim 3 further limits the analysis information management method of claim 1 by requiring the database stored in the service center to store

analysis parameters related to reagents from a plurality of reagent suppliers.
The final rejection does not address this claim with specificity, and thus no *prima
facie* case of unpatentability has been made out. Accordingly, the Appellants
respectfully request reversal of the rejection of claim 3.

Claim 6

Dependent claim 6 further limits the analysis information management
method of claim 1 by requiring that, when a reagent supplier supplies a novel
reagent or a reagent in a new lot to a user of the requesting automatic analyzing
apparatus, the reagent supplier registers the database stored in the service
center with information related to the reagent, such as the reagent, automatic
analyzing apparatuses capable of using the reagent, and analysis parameters for
the reagent prior to supply. The final rejection does not address the limitations of
claim 6 with any specificity, and thus no *prima facie* case of anticipation is made
out. Accordingly, the Appellants respectfully request reversal of the rejection of
claim 6.

Claim 8

Dependent claim 8 further limits the analysis information management
method of claim 1 by requiring the service center, upon determination that the
result of analysis on an accuracy management sample transferred thereto from
the automatic analyzing apparatus was derived using newly set analysis
parameters, to summarize the result of determination in a report, and to transmit

the report to the automatic analyzing apparatus through the communication line.
The final rejection does not address the limitations of claim 8, and thus no *prima facie* case of anticipation is made out. Accordingly, the Appellants respectfully request reversal of the rejection of claim 8.

Claim 9

Dependent claim 9 further limits the analysis information management method defined in claim 1, by requiring that each time the service center receives the result of analysis on a control sample from the requesting automatic analyzing apparatus, the service center calculates the statistical deviation from the standard value, and transmits the results of analysis to the requesting automatic analyzing apparatus through the communication line if any defect is recognized based on the determination. The final rejection does not address the limitations of claim 9, and thus no *prima facie* case of anticipation is made. Accordingly, the Appellants respectfully request reversal of the rejection of claim 9.

Claim 10

Dependent claim 10 further limits the analysis information management method of claim 9 by requiring that, when no defect is recognized in the result of analysis, the service center stores the result of analysis, periodically creates a report, and transmits the report to the automatic analyzing apparatuses through the communication lines. The limitations of claim 9, however, are not addressed

in the final rejection, and thus no *prima facie* case of anticipation is made.
Accordingly, the Appellants respectfully request reversal of the rejection of
claim 10.

Claim 11

Dependent claim 11 further limits the analysis information management
method of claim 1, by requiring the service center to periodically calculate the
standard value, and to transmit the standard value to the automatic analyzing
apparatuses through the communication lines as technical information. The
limitations of claim 11 are not addressed in the final rejection, however, and thus
no *prima facie* case of anticipation is established. Accordingly, the Appellants
respectfully request reversal of the rejection of claim 11.

Claim 12

Dependent claim 12 further limits the analysis information management
method of claim 1 by requiring the service center to store and manage, by
version, programs for controlling the automatic analyzing apparatuses
administered thereby, and to automatically install a program of a requested
version in response to a request from an automatic analyzing apparatus
administered thereby. The final rejection, however, does not address the
limitations of claim 12, and particularly does not assert any passage in JP '657
relating to the storing, managing by version, or installation of any program for
controlling the automatic analyzing apparatuses administered by the service

center. Accordingly, the Appellants respectfully request reversal of the rejection

of claim 12.

C. Claims 1-3, 6, and 8-12 stand rejected under 35 U.S.C. §102(e) as being

anticipated by Fritchie, U.S. Patent No. 6,022,746 (Fritchie).

Claim 1

The final rejection refers to the "appropriate paragraph of the 5/31/05

Office action" with respect to this rejection, and thus the Appellants will refer to

that Office Action in the following argument.

The paragraph cited by the Examiner rejected claims 1-3 and 6-12 as they

existed following the Amendment filed December 10, 2004. As such, on its face,

the final rejection of claims 1-3, 6 and 8-12 over Fritchie (claim 7 has been

canceled) is deficient because the current claims have not been read on Fritchie

for the purpose of making a proper determination.

In addition, the paragraph cited by the Examiner simply states:

> Fritchie et al. teach a method of allocating resources of an
> automated analyzer to optimize analysis. Col. 5 lines 19 through
> column 6 teach system (10) software that tracks the reagent
> inventory and notifies the user when needed. The device also
> tracks the calibration status of test and lot numbers for each of the
> instruments (12A-12D).

Accordingly, claim 1 is clearly patentably distinguishable from Fritchie.

Specifically, Fritchie does not address any of the limitations set forth in the

creating or transferring steps set forth in claim 1. Further, Fritchie does not disclose any of the limitations set forth in the "wherein" paragraph of claim 1.

Moreover, Fritchie does not disclose a service center that calculates, based on stored information on the results of analyses for each of plural facilities or for each of plural automatic analyzing apparatuses, a statistical standard value defined for the results of analyses on control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center, as required by claim 1.

Also, as previously argued and acknowledged by the Examiner, Fritchie does not disclose or suggest the step of calculating a statistical deviation for the result of analysis from the standard value, or determining, based on the calculated statistical deviation, whether the analysis parameters used in the analysis are correct.

For each of these reasons, the Appellants respectfully submit that the rejection of claim 1 over Fritchie should be reversed.

Claim 2

Dependent claim 2 further limits the analysis information management method of claim 1 by requiring the automatic analyzing apparatus to automatically set the transferred analysis parameters. The final rejection does not address this feature of the invention, and thus no *prima facie* case has been established for the rejection of claim 2. Accordingly, the Appellants request reversal of the rejection of the dependent claim 2.

Claim 3

Dependent claim 3 further limits the analysis information management method of claim 1 by requiring the database stored in the service center to store analysis parameters related to reagents from a plurality of reagent suppliers. The final rejection does not address this claim with specificity, and thus no *prima facie* case of unpatentability has been made out. Accordingly, the Appellants respectfully request reversal of the rejection of claim 3.

Claim 6

Dependent claim 6 further limits the analysis information management method of claim 1 by requiring that, when a reagent supplier supplies a novel reagent or a reagent in a new lot to a user of the requesting automatic analyzing apparatus, the reagent supplier registers the database stored in the service center with information related to the reagent, such as the reagent, automatic analyzing apparatuses capable of using the reagent, and analysis parameters for the reagent prior to supply. The final rejection does not address the limitations of claim 6 with any specificity, and thus no *prima facie* case of anticipation is made out. Accordingly, the Appellants respectfully request reversal of the rejection of claim 6.

Claim 8

Dependent claim 8 further limits the analysis information management method of claim 1 by requiring the service center, upon determination that the result of analysis on an accuracy management sample transferred thereto from the automatic analyzing apparatus was derived using newly set analysis parameters, to summarize the result of determination in a report, and to transmit the report to the automatic analyzing apparatus through the communication line. The final rejection does not address the limitations of claim 8, and thus no *prima facie* case of anticipation is made out. Accordingly, the Appellants respectfully request reversal of the rejection of claim 8.

Claim 9

Dependent claim 9 further limits the analysis information management method defined in claim 1, by requiring that each time the service center receives the result of analysis on a control sample from the requesting automatic analyzing apparatus, the service center calculates the statistical deviation from the standard value, and transmits the results of analysis to the requesting automatic analyzing apparatus through the communication line if any defect is recognized based on the determination. The final rejection does not address the limitations of claim 9, and thus no *prima facie* case of anticipation is made. Accordingly, the Appellants respectfully request reversal of the rejection of claim 9.

Claim 10

Dependent claim 10 further limits the analysis information management method of claim 9 by requiring that, when no defect is recognized in the result of analysis, the service center stores the result of analysis, periodically creates a report, and transmits the report to the automatic analyzing apparatuses through the communication lines. The limitations of claim 9, however, are not addressed in the final rejection, and thus no *prima facie* case of anticipation is made. Accordingly, the Appellants respectfully request reversal of the rejection of claim 10.

Claim 11

Dependent claim 11 further limits the analysis information management method of claim 1, by requiring the service center to periodically calculate the standard value, and to transmit the standard value to the automatic analyzing apparatuses through the communication lines as technical information. The limitations of claim 11 are not addressed in the final rejection, however, and thus no *prima facie* case of anticipation is established. Accordingly, the Appellants respectfully request reversal of the rejection of claim 11.

Claim 12

Dependent claim 12 further limits the analysis information management method of claim 1 by requiring the service center to store and manage, by version, programs for controlling the automatic analyzing apparatuses

administered thereby, and to automatically install a program of a requested

version in response to a request from an automatic analyzing apparatus

administered thereby. The final rejection, however, does not address the

limitations of claim 12, and particularly does not assert any passage in Fritchie

relating to the storing, managing by version, or installation of any program for

controlling the automatic analyzing apparatuses administered by the service

center. Accordingly, the Appellants respectfully request reversal of the rejection

of claim 12.

VIII.   <u>CONCLUSION</u>

For the foregoing reasons, the Appellants respectfully submit that the rejection of the claims on appeal should be reversed and the application allowed.

The Appellants are electronically filing this response. Payment of the $510.00 fee for this Brief in support of an appeal, as well as the four-month extension fee required to render this Appeal Brief timely.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, or credit any overpayment of fees, to the deposit account of Mattingly, Stanger, Malur & Brundidge, P.C., Deposit Account No. 50-1417 (referencing attorney docket no. KAS-157).

Respectfully submitted,

MATTINGLY, STANGER, MALUR & BRUNDIDGE, P.C.

_____/Daniel J. Stanger/_____
Daniel J. Stanger
Registration No. 32,846

DJS/sdb
(703) 684-1120

IX.   CLAIMS APPENDIX

1. An analysis information management method using a service center connected through communication lines to a plurality of automatic analyzing apparatuses used in a plurality of facilities, said service center having a database for storing analysis parameters related to a plurality of reagents for use in the plurality of automatic analyzing apparatuses used in the plurality of facilities, the method comprising the steps of:

creating, by said service center responsive to a request from one of said automatic analyzing apparatuses, a list of reagents available in said one automatic analyzing apparatus from information on reagents stored in said database, and supplying said one automatic analyzing apparatus with the list through a communication line;

transferring, by said service center responsive to a selection of an associated reagent from said list, made by a user of said one automatic analyzing apparatus, analysis parameters, according to which a test is to be carried out on a testing item to be analyzed using the selected reagent, to said one automatic analyzing apparatus through said communication line;

wherein said service center classifies and stores information, including results of calibrations measured by said automatic analyzing apparatuses, results of analyses on control samples, reagents used in analyses, and analysis parameters, for tests carried out in each facility or for each automatic analyzing apparatus, wherein the results of analyses on said control samples are derived

from analyses of said control samples using the same reagents in all automatic

analyzing apparatuses in all facilities administered by said service center;

calculating, by said service center based on the stored information on the

results of analyses for each facility or for each automatic analyzing apparatus, a

statistical standard value defined for said results of analyses on said control

samples using the same reagents in all automatic analyzing apparatuses in all

facilities administered by said service center;

adding said selected reagent to a control sample in said one automatic

analyzing apparatus;

analyzing a control sample by said one automatic analyzing apparatus;

calculating, by said service center, a statistical deviation for the result of

analysis from said standard value for evaluation; and

determining, based on the calculated statistical deviation, whether the

analysis parameters used in the analysis are correct.

2. An analysis information management method according to claim 1,

wherein:

said automatic analyzing apparatus automatically sets the

transferred analysis parameters.

3. An analysis information management method according to claim 1,

wherein:

said database stores analysis parameters related to reagents from a plurality of reagent suppliers.

4. – 5. (Canceled)

6. An analysis information management method according to claim 1, wherein:

when a reagent supplier supplies a novel reagent or a reagent in a new lot to a user of said one automatic analyzing apparatus, said reagent supplier registers said database with information related to said reagent, such as said reagent, automatic analyzing apparatuses capable of using said reagent, and analysis parameters for said reagent prior to supply.

7. (Canceled)

8. An analysis information management method according to claim 1, wherein:

said service center, upon determination that the result of analysis on an accuracy management sample transferred thereto from said one automatic analyzing apparatus was derived using newly set analysis parameters, summarizes the result of determination in a report, and transmits the report to said one automatic analyzing apparatus through the communication line.

9. An analysis information management method according to claim 1, wherein:

      each time said service center receives the result of analysis on a control sample from said one automatic analyzing apparatus, said service center calculates said statistical deviation from said standard value, and transmits the result of analysis to said one automatic analyzing apparatus through the communication line if any defect is recognized based on said determination.

10. An analysis information management method according to claim 9, wherein:

      when no defect is recognized in the result of analysis, said service center stores the result of analysis, periodically creates a report, and transmits the report to the automatic analyzing apparatuses through the communication lines.

11. An analysis information management method according to claim 1, wherein:

      said service center periodically calculates said standard value, and transmits said standard value to the automatic analyzing apparatuses through the communication lines as technical information.

12. An analysis information management method according to claim 1, wherein:

said service center stores and manages, by version, programs for controlling the automatic analyzing apparatuses administered thereby, and automatically installs a program of a requested version in response to a request from an automatic analyzing apparatus administered thereby.

13. – 15. (Canceled)

X.   **<u>EVIDENCE APPENDIX</u>**

None

XI.   RELATED PROCEEDINGS INDEX

None